The Examiner noted that Claims 30 and 32 depended upon canceled claims, and applicants have accordingly corrected the error.

The Examiner rejected Claims 1 to 9, 12, 13, 16 to 23, 25 and 27 to 33 under 35 U.S.C. §112, ¶1, asserting that applicants' disclosure of the claimed invention failed to comply with the written description requirement for failing to describe how polyvinylpyrrolidone was finely dispersed in the polyvinyl acetate. Favorable reconsideration of the Examiner's position and withdrawal of the respective rejection is respectfully solicited in light of the following remarks.

An application need not teach, and preferably omits, that which is well known in the art.[2] Applicants have enclosed herewith a copy of a U.S. patent of *Kolter et al.*, ie. US 6,066,334, which illustrates a prior art procedure for obtaining a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone and which corroborates that the manner in which polyvinylpyrrolidone was finely dispersed in the polyvinyl acetate was known in the art at the time applicants' made their invention. In this context it is also respectfully noted that applicants' employed in the representative examples which are described in the application a commercially available product, ie. Kollidon® SR, which further corroborates that formulated mixtures of polyvinyl acetate and polyvinylpyrrolidone in which polyvinylpyrrolidone was finely dispersed in the polyvinyl acetate were known in the art at the time applicants made their invention.

Also, to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail to convey to one skilled in the art that, as of the filing date sought, the applicant had possession of the claimed invention.[3] Possession of the claimed invention can be shown by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention,[4] and possession of the claimed invention can in particular be shown by the descrip-

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2) Cf. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

3) See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991).

4) *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

tion of an actual reduction to practice of the invention.[5] Accordingly, applicants' detailed description of examples which is set forth in the application is a clear showing that applicants had possession of the invention when the application was filed.

In light of the foregoing it is respectfully requested that the rejection of Claims 1 to 9, 12, 13, 16 to 23, 25 and 27 to 33 under 35 U.S.C. §112, ¶1, be withdrawn. Favorable action by the Examiner is solicited.

The Examiner reiterated the position that Claims 1 to 9, 12, 13, 16 to 23, 25 and 27 to 33 were unpatentable under 35 U.S.C. §103(a) in light of the teaching of ***Ortega et al.*** (US 4,837,032) pointing out, inter alia, that the manner in which a composition was made carried no patentable weight.

It is respectfully noted that applicants' claims not only relate to a composition[6] but also relate to a certain method[7] and and to a particular process for the manufacture of certain dosage forms.[8] As concerns applicants' method claim it is respectfully urged that not only the materials used and the nature of the specific process employed but also the particular result which is obtained must be considered when determining whether a claimed method is obvious within the meaning of Section 103,[9] and essentially the same applies where the method is a process for the manufacture of a certain product.[10] Where applicants' claims relating to the method and to the process are concerned the rationale underlying the Examiner's respective rejection is therefore not well taken.

Applicants' process claims require inter alia that a certain formulated mixture of polyvinyl acetate (PVA) and polyvinylpyrrolidone (PVP) in which the PVP is finely dispersed in the PVA be used, and that the respective formulated PVA-PVP mixture, in mixture with at least one active ingredient, be granulated in the absence of a

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5) See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).

6) Cf. Claims 17 to 23 and 33.

7) Cf. Claim 25.

8) Cf. Claims 1 to 9, 12, 13, 16 and 27 to 32.

9) *In re Dillon*, 919 F.2d 688, 695, 16 USPQ2d 1897, 1903 (Fed. Cir. 1990) (*en banc*), *cert. denied*, 500 U.S. 904 (1991).

10) See e.g. *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995); *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996).

solvent at a temperature of from 40 to 130°C. As previously explained by applicants and as illustrated in the examples described in the application, the mixture which is dry-granulated comprises, accordingly (a) particles of the formulated PVA-PVP mixture and (b) particles of the active ingredient.[11] The procedure which is used in accordance with the teaching of ***Ortega et al.*** differs from applicants' process in various aspects.

Most pertinently, ***Ortega et al.***'s process comprises wet granulating a mixture comprising an *acid-insoluble polymer* and a film former such as PVP.[12] The acid insoluble polymer which is employed in this stage of ***Ortega et al.***'s procedure is *different from PVA* as is immediately apparent from the information on acid insoluble polymers provided in col. 3, indicated lines 39 to 48, of the reference. The granules which are formed in this stage of ***Ortega et al.***'s process are therefore distinctly different from the formulated PVA-PVP mixture which is employed in accordance with applicants' process. Further, ***Ortega et al.***'s process comprises *mixing* the granules obtained in the wet granulation stage with additional film former such as PVP and with a *water-insoluble polymer* such as, inter alia, PVA and a lubricant.[13] The resulting physical mixture of the granules, the water-insoluble polymer and the lubricant may then be compressed.[14] On the one hand, the prior art procedure clearly fails to include a stage in which a mixture comprising PVA and PVP is granulated, on the other hand, the prior art clearly fails to suggest or imply the utilization of a formulated PVA-PVP mixture according to applicants' constituent (a) in a granulation.

In order to establish a *prima facie* case of obviousness, three basic criteria have to be met:[15]

(1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings,

(2) there must be a reasonable expectation of success, and

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11) Cf. e.g. page 3 of applicants' paper dated March 07, 2005.

12) Cf. in particular col. 4, indicated lines 1 to 7, of ***US 4,837,032***.

13) Cf. in particular col. 4, indicated lines 7 to 10, in conjunction with col. 3, indicated lines 28 to 38, of ***US 4,837,032***.

14) Cf. col. 4, indicated lines 10 to 12, of ***US 4,837,032***.

15) Cf. MPEP §2143.

(3) the prior art reference or the combined references must teach or suggest all of the claim limitations.

Additionally, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and cannot be based on applicants' disclosure.[16] ***Ortega et al.*** convey nothing which would provide the suggestion or motivation which is necessary for a person of ordinary skill in the art to effect the changes which are necessary to arrive at the elements of applicants' claims. Moreover, the teaching of ***Ortega et al.*** clearly falls short from teaching or suggesting all of the limitations of applicants' process. Accordingly, at least two of the three basic criteria are not met here and the reference cannot reasonably be taken to establish that the subject matter of applicants' respective claims was prima facie obvious within the meaning of Section 103(a).

Correspondingly, applicants' composition claims require that the dosage form comprise the respective formulated PVA-PVP mixture, ie. each part or particle of the dosage form comprises both PVA and PVP, the PVP being present finely dispersed in the PVA. ***Ortega et al.***'s tablets, in contrast, comprise PVP particles and PVA particles in compressed form. This does not, however, suggest or even imply that PVP is taken up by the PVA particles to form a particle as encountered in the formulated PVA-PVP mixture which is one of the constituents of applicants' dosage form. The Examiner's attention is, in this context, respectfully drawn to the statements of ***Kolter et al.***: *"The two polymers [PVP and PVA] are not miscible with one another ... so that simple combination, for example by a homogeneous melt, is not possible."*[17] This statement further corroborates that a wet granulation of discrete PVP particles and PVA particles as taught by ***Ortega et al.*** does not result in the composition which is defined in applicants' respective claims. Moreover and as stated in the foregoing, ***Ortega et al.*** convey nothing which would provide the suggestion or motivation which is necessary for a person of ordinary skill in the art to effect the changes which are necessary to arrive at the elements of applicants' dosage form, and the teaching of ***Ortega et al.*** clearly fails to teach or suggest all of the limitations of applicants' respective claims. Again, at least two of the three basic criteria are not met, and the reference

16) *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).
17) Cf. col. 2, indicated lines 57 to 60, of *US 6,066,334*.

cannot reasonably be taken to establish that the dosage forms referenced in applicants' claims were prima facie obvious within the meaning of Section 103(a).

In light of the foregoing it is respectfully urged that the rejection of Claims 1 to 9, 12, 13, 16 to 23, 25 and 27 to 33 under 35 U.S.C. §103(a) based on the teaching of ***Ortega et al.*** be withdrawn. Favorable action is solicited.

The Examiner also rejected Claims 1 to 9, 12, 13, 16 to 23, 25 and 27 to 33 under 35 U.S.C. §103(a) as being unpatentable in light of the teaching of ***Ortega et al.*** (ibid.) when taken in view of the disclosure of ***Noda et al.*** (US 5,389,380), applying the secondary reference for teaching a theophylline composition which contains lactose or starch or mannitol excipient. ***Noda et al.***'s disclosure adds nothing to the teaching of ***Ortega et al.*** which could reasonably supplement the suggestion or motivation which is necessary for a person of ordinary skill in the art to modify ***Ortega et al.***'s tablets, or the process employed in accordance with ***Ortega et al.***'s teaching, as is necessary to arrive at the dosage forms, or the method or the process which is defined in applicants' claims. The disclosure of ***Noda et al.*** is equally unsuited to teach or suggest any of the limitations of applicants' claims which are missing from the teaching of ***Ortega et al.*** Even when the disclosure of ***Noda et al.*** is included in the consideration, at least two of the three basic criteria for establishing a prima facie case of obviousness are not met, and the references cannot reasonably be taken to establish that the subject matter of applicants' respective claims was prima facie obvious within the meaning of Section 103(a).

In light of the foregoing it is respectfully urged that the rejection of Claims 1 to 9, 12, 13, 16 to 23, 25 and 27 to 33 under 35 U.S.C. §103(a) based on the teaching of ***Ortega et al.*** and the disclosure of ***Noda et al.*** be withdrawn. Favorable action is solicited.

REQUEST FOR EXTENSION OF TIME:

It is respectfully requested that a *two* month extension of time be granted in this case. The respective *$450.00* fee is paid by credit card (Form PTO-2038 enclosed).

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Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit Account No. 14.1437. Please credit any excess fees to such deposit account.

Respectfully submitted,
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Encl.: CLAIM AMENDMENTS (Appendix I)
Kolter et al., US 6,066,334

JDV/BAS